K014164

MAR 1 2 2002

Summary of Safety and Effectiveness
for
Great Toe Implant System

This safety and effectiveness summary for the Great Toe Implant System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :

Harmos Orthopedic Inc.
3238 Player's Club Circle
Memphis, TN 38125
901-748-1900

Contact Person :

Richard W. Woods
MedCon LLC
1002 Frederick Road
Catonsville, MD 21228
(410) 744-8367
FAX (410) 744-8368

Date Prepared: December 17, 2001

2. Tradename: Great Toe Implant System
Common Name: Great Toe System
Classification Name: Prosthesis, Toe, Hemi-, Phalangeal (888.3730)

3. Predicate or legally marketed devices which are substantially equivalent :

- Swanson Titanium Great Toe Implant System (Dow Corning Wright)
- Metallic Hemiarthroplasty Resurfacing Prosthesis (BioPro)
- Futura Biomedical Metal Hemi Toe Implant System (Futura Biomedical)

4. Description of the device :

The Great Toe Implant System is a one piece implant to supplement first metatarsal phalangeal joint arthroplasty. The implant is designed to replace the base of the proximal phalanx and provide a smooth articular surface for the adjacent metatarsal head. It is available in several sizes to accommodate variations in anatomy. Primary fixation is via a press fit.

Materials: The devices are manufactured from CoCrMo alloy per ASTM and ISO standards.

Function: The system functions to provide pain relief and improved function to the first metatarsal joint that has been damaged by inflammatory arthritis.

5. Intended Use:

The Great Toe Implant System is indicated for use in the treatment of patients with inflammatory arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head, along with the following clinical conditions: hallux valgus, hallux rigidus and an unstable or painful MTP joint.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the Great Toe Implant System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2002

Mr. Richard W. Woods
Harmos Orthopedic, Inc.
c/o MedCon LLC
1002 Frederick Road
Cantonsville, Maryland 21228

Re: K014164
Trade/Device Name: Great Toe Implant System
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: December 17, 2001
Received: December 19, 2001

Dear Mr. Woods:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

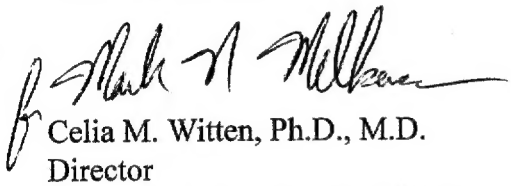
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) : K014164

Device Name : Great Toe Implant System

Indications For Use :

The Great Toe Implant System is indicated for use in the treatment of patients with inflammatory arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head, along with the following clinical conditions: hallux valgus, hallux rigidus and an unstable or painful MTP joint.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X
(PER 21 CFR 801.109)

OR

Over-the-counter use ______

(optional format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014164